PHILIP MORRIS CLINICAL MILESTONES

Philip Morris Project #:	EHCK6/02/04		
MDS Study #:	AA03468		
Clinical Site(s) Involved:	LNK		
Milestone:	Scheduled Completion Date:	Actual Completion Date:	Comments:
Pre-Study Proposal Due			These milestones were completed prior to the compilation of this worksheet. All tasks have been completed but specific dates are not readily available.
Propose Recruiting Ads			
Ad Response/Approval to MDS			
Expedited IRB Review of Ads, Text			
Expedited IRB Review of Ads, Radio			
Final Documents to IRB			
IRB Meeting			
Proposed Study Fee to Philip Morris			
Pre-Study PA Completed			
Recruiting Start Date			
Paper Ads to Start			
Radio Ads to Start			
MDS Internal Expectations Meeting			
Client Study Initiation Visit			
Screening(s)			
Physical Exams			
Call-Outs			
Spec and T/E Complete			
Full Study PA Completed			
Name List Complete			
Check-in	4-May-2004	4-May-2004	Second confinement check-in = 11 May 04
Baseline	5-May-2004	5-May-2004	
Check-out	6-May-2004	6-May-2004	Second confinement check-out = 13 May 04
Return(s)	4-Aug-2004		LPLV
QC Issues Final Audit	9-Aug-2004		
Clinical DB Lock	18-Aug-2004		
SM Form to CCRW	27-Aug-2004		
CCSR to SM for review	1-Sep-2004		
SM Respond to CCSR	6-Sep-2004		
CCSR to SM for final review	8-Sep-2004		
Urine deviations to PM USA	8-Sep-2004		
SM finalizes CCSR	10-Sep-2004		
CCSR to QA	13-Sep-2004		
QA completes review of CCSR	23-Sep-2004		
QA issues audit of CCSR	24-Sep-2004		
SM Response to QA audit of CCSR	27-Sep-2004		
SM send list of deviations to PM USA	29-Sep-2004		
CCRW gets corrected CCSR to SM	29-Sep-2004		
PM USA comments to MDS on deviations	31-Sep-2004		
SM verifies CCSR and sends to CCRW	1-Oct-2004		
CCSR to QA	4-Oct-2004		
QA completes review of CCSR	11-Oct-2004		
QA issues audit of CCSR	12-Oct-2004		
SM Response to QA audit of CCSR	14-Oct-2004		
CCRW gets corrected CCSR to SM	18-Oct-2004		
SM verifies CCSR and sends to CCRW	19-Oct-2004		
CCSR to QA	20-Oct-2004		
CCSR Released as Final	21-Oct-2004		
CCSR signed by PI	25-Oct-2004		

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PHILIP MORRIS DATA MANAGEMENT/STATS MILESTONES

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MDS Study #:	AA03468		
Clinical Site(s) Involved:	LNK		
Milestone:	Scheduled Completion Date:	Actual Completion Date:	Comments:
Clinical DB Lock	18-Aug-2004		
Pharmacy Log Data to CRF Associate	26-Jul-2004	30-Jul-2004	
Pharmacy Log Data Entry Complete	13-Aug-2004		
Edit Checks to Begin	20-Aug-2004		
Edit Checks Completed	3-Sep-2004		
Monitoring of Data Complete	30-Sep-2004		
Monitoring Close-out Visit	14-Oct-2004		
COHb Results Available	1-Sep-2004		
Initial Creatinine Results Available	1-Sep-2004		
Amount Excreted Calculated	8-Sep-2004		
Run Bioplausibility Flowchart #3	8-Sep-2004		
Creatinine Listing to Philip Morris	8-Sep-2004		
CPD Listing to PM USA	8-Sep-2004		
Philip Morris decision re: re-assays	10-Sep-2004		
PM USA comments back on urine deviation & CPD	10-Sep-2004		
Re-assays completed	17-Sep-2004		
All Creatinine Results Available	20-Sep-2004		
Run Bioplausibility Flowchart #3	22-Sep-2004		
All Creatinine Results to PM for review	22-Sep-2004		
PM decision on analysis exclusion	24-Sep-2004		
Send Listing for Nicotine, Cot, TransOHCot, NicGluc	6-Oct-2004		
Send Data Listing for 3-HPMA	6-Oct-2004		
Send Data Listing for SPMA	6-Oct-2004		
Send Data Listing for CotGluc, TransOHCotGluc	6-Oct-2004		
Send Data Listing for NNAL Total	11-Oct-2004		
Send Data Listing for NNAL Free	11-Oct-2004		
Send Data Listing for 1-OHP	6-Oct-2004		
Send Draft Listings of Clinical data to QA	8-Sep-2004		
Send Draft Listings of Clinical data to PM USA	29-Sep-2004		monitoring of the data will be complete 30 Sep 04
Statistical DB Lock	21-Oct-2004		

NOTE: Milestones need to be calculated for the individual data listings requested by Philip Morris. These listings include:

	Biomarker:	Lock Date:	
	NNAL Total	24-Sep-04	
	NNAL Free	27-Sep-04	
	3-HPMA	17-Sep-04	
Nicotine, Cot, TransOHCot, NicGluc		3-Sep-04	
	1-OHP	22-Sep-04	
CotGluc, TransOHCotGluc		21-Sep-04	
	SPMA	17-Sep-04	
	Clinical Data	3-Sep-2004	

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PHILIP MORRIS REPORTING MILESTONES

Philip Morris Project #:	FHCK6/02/04		
MDS Study #:	AA03468		
Clinical Site(s) Involved:	LNK		
Milestone:	Scheduled Completion Date:	Actual Completion Date:	Comments:
Clinical DB Lock	18-Aug-2004		
CCSR Released as Final	21-Oct-2004		
Finalize Reportable Creatinine Results	22-Sep-2004		
Analytical DB Lock	1-Oct-2004		
Data Listings & Bio Reports Accepted	20-Oct-2004		
SAP Finalized	1-Oct-2004		
Send Draft Tables and Graphs to PM USA	15-Oct-2004		
Statistical DB Lock	21-Oct-2004		
TLG's Finalized	**29-Oct-2004**		
Final TLG's to Reporting	29-Oct-2004		
Final TLG's to QA	5-Nov-2004		
Medical Writing Start; Protocol Sections, Methods, etc. Complete	1-Nov-2000		
Write Results Section "A", MW Complete	4-Nov-2004		
Write Results Section "B", QC of Results Section "A", Peer QC of Medical Writing	8-Nov-2004		
Write Results Section "C", QC of Results Section "B" and Medical Writing	11-Nov-2004		
Write Results Section "D", QC of Results Section "C"	16-Nov-2004		
QC of Results Section "D"	18-Nov-2004		
Send "Working Draft" to PMSM	19-Nov-2004		This is 3 weeks from final TLG's.
PMSM Review of "Working Draft", MDS Stats Review of Working Draft, Compile and QC Appendices	30-Nov-2004		
Collaboration Between PMSM and MDSW	7-Dec-2004		
Write Results, Conclusions and Relevant Synopsis Sections	10-Dec-2004		
Director, MW and Stats review of "Complete Draft", QC of Results, Conclusions and Synopsis	15-Dec-2004		
Address Review Comments	16-Dec-2004		"Complete Draft" to QA
QA entire report	12-Jan-2005		

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Clinical Site(s) Involved:	LNK		
Milestone:	Scheduled Completion Date:	Actual Completion Date:	Comments:
Address QA comments	20-Jan-2005		
Send "Complete Draft" to PMSM	**21-Jan-2005**		This is 12 weeks from final TLG's with three holidays accounted for.
"Complete Draft" review by Philip Morris, Revisions Sent to MDS	18-Feb-2005		
Implementation of Revisions**	4-Mar-2005		
QA entire report	11-Mar-2005		
Address QA comments	25-Mar-2005		
"Final Report" Sent to PMSM for Approval	28-Mar-2005		
PM Review of Final Report and Approval and Communication to MDS	4-Apr-2005		
Collection of Signatures	7-Apr-2005		
"Signed Final Report" Issued	8-Apr-2005		
NOTE:			
Did not count the 25th, 26th, and 29th November for Thanksgiving			
Did not count the 23rd, 24th, 27th, 30th, 31st of DEC and the 3rd of JAN for Christmas and New Year's			

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